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Date of Deposit May 27, 2003

PATENT
Attorney Docket No.: 15270J-005913US
Client Reference No.: 209-US-NEW6C3

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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

By:

Rosemarie L. Celli
Rosemarie L. Celli

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,953

Filed: November 28, 2000

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Examiner: Christopher J. Nichols

Art Unit: 1647

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. A copy of citation no. 187 is submitted herewith. In accordance with 37 CFR §1.98(d), copies of the other cited references can be found in Application No. 09/585,817, filed June 1, 2000 (Attorney Docket No. 015270-005910US).

A copy of the International Search Report issued in the International (PCT) application corresponding to the above-identified application is submitted herewith.

The Assignee of the instant application is a licensee of U.S. Patent No. 5,688,651, which is directed in part to subject matter related to the instant application. U.S. Patent No. 5,688,651 is now undergoing examination reissue as Application No. 09/441,140. The initial

IDS filed October 3, 2001 cited U.S. Patent No. 5,688,651 as Cite no. 16. This supplemental IDS cites U.S. Application No. 09/441,140 as Cite No. 283.

"Grant Application; Raso, Immunology of Alzheimer's Disease', 1/1998," cited by the Examiner in Application No. 09/579,690, is submitted herewith as cite no. 304.

Application No. 09/579,690 is a commonly owned copending application directed to subject matter related to the instant application. Applicant believes "1/1998" is not the publication date as alleged by the Examiner, but refers to the grant funding cycle. It is Applicant's further believe the date of public accessibility, if any, is unknown. Applicant wishes] to bring to the Examiner's attention that a copy of a grant application believed to have been submitted by Victor Raso for NIH Grant 1 R43 AGI 5746-01 on August 29, 1997 was previously submitted in the initial IDS submitted on October 3, 2001 as cite no. 144. Cite no. 144 is a redacted version of cite no. 304. Applicant obtained cite no. 144 under the Freedom of Information Act (FOIA). It is believed that the grant proposal would not have been accessible under FOIA before April 2, 1998, but the exact date of public accessibility, if any, is not known to Applicant.

Applicant also cites commonly owned copending applications directed to related subject matter:

09/201,430 filed 11/30/98;
09/497,553 filed 02/03/00;
09/724,477 filed 11/28/00;
09/723,927 filed 11/28/00;
09/724,762 filed 11/28/00;
09/724,102 filed 11/28/00;
09/724,489 filed 11/28/00;
09/322,289 filed 05/28/99;
09/723,713 filed 11/27/00;
09/723,760 filed 11/27/00;
09/724,319 filed 11/27/00;
09/723,384 filed 11/27/00;
09/724,495 filed 11/27/00;
10/429,216 filed 05/02/03;

09/580,015 filed 05/26/00;
09/724,940 filed 11/28/00;
09/724,961 filed 11/28/00;
09/580,018 filed 05/26/00;
09/724,552 filed 11/28/00;
09/723,544 filed 11/28/00;
09/724,273 filed 11/28/00;
09/724,551 filed 11/28/00;
09/724,288 filed 11/28/00;
09/580,019 filed 05/26/00;
09/723,765 filed 11/28/00;
09/724,291 filed 11/28/00;
09/204,838 filed 12/03/98;
09/724,921 filed 11/28/00;
09/724,929 filed 11/28/00;
09/585,817 filed 06/01/00;
09/724,567 filed 11/28/00;
09/724,575 filed 11/28/00;
09/724,953 filed 11/28/00;
09/724,570 filed 11/28/00;
09/585,656 filed 06/01/00;
09/723,766 filed 11/27/00;
09/723,725 filed 11/27/00;
09/579,690 filed 05/26/00;
09/979,701 filed 03/13/01 (U.S. National Stage of PCT/US00/14810 filed 05/26/00);
09/979,952 filed 04/04/02 (U.S. National Stage of PCT/US00/15239 filed 06/01/00); and,
09/980,568 filed 03/12/02 (U.S. National Stage of PCT/US00/15302 filed 06/01/00).

Applicant also cites the following copending application directed to related subject matter but subject to different assignment:

10/010,942 filed 12/06/01;
10/232,030 filed 08/30/02;
60/444,150 filed 02/01/03; and
10/388,214 filed 03/12/03.

Applicant further cites the following commonly owned abandoned applications directed to related subject matter:

60/067,740 filed 12/02/97;
60/080,970 filed 04/07/98;
60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
60/137,010 filed 06/01/99;
60/137,047 filed 06/01/99; and,
60/136,655 filed 05/28/99.

Applicant also cites the following abandoned application directed to related subject matter but subject to different assignment:

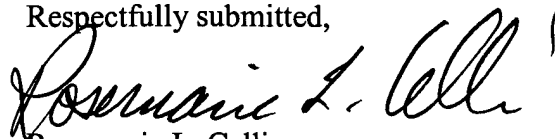
60/251,892 filed 12/06/00.

Applicant points out that the following applications are now commonly assigned but were previously subject to different assignment than the present application:

60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
09/204,838 filed 12/03/98;
09/724,921 filed 11/28/00; and,
09/724,929 filed 11/28/00.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance. Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Rosemarie L. Celli

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PATENT

Attorney Docket No.: 15270J-005913US

Client Reference No.: 209-US-NEW6C3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,953

Filed: November 28, 2000

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Examiner: Christopher Nichols

Art Unit: 1647

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The references cited on the attached PTO/SB/08B form are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference

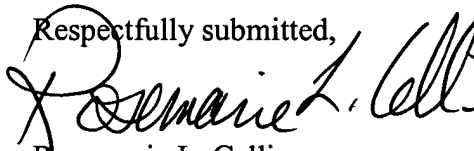
should be made that the information and references cited are prior art merely because they are in this statement.

This IDS is being filed after the first office action was mailed but before the mailing date of the final office action or notice of allowance. Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

CERTIFICATION

I hereby certify that no item of information contained in the Supplemental Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the undersigned's knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Supplemental Information Disclosure Statement.

Respectfully submitted,



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PTO/SB/08A (10-01)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 10

Complete if Known

Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	340	2002/0162129 A1	10-31-2002	Lannfelt	
	326	2002/0136718 A1	09-26-2002	Raso	
	325	2001/0102261 A1	08-01-2002	Raso	
	306	6,417,178 B1	07-09-2002	Klunk et al.	
	342	2002/0009445 A1	01-24-2002	Du et al.	
	267	6,294,171 B2	09-25-2001	McMichael	
	234	6,284,221 B1	09-04-2001	Schenk, et al.	
	300	2001/0018053 A1	08-30-2001	McMichael	
	230	6,262,335 B1	07-17-2001	Hsiao et al.	
	345	2002/0077288 A1	06-21-2001	Frangione	
	231	6,114,133	09-05-2000	Seubert et al.	
	221	5,989,566	11-23-1999	Cobb et al.	
	346	5,935,927	08-10-1999	Vitek et al.	
	321	5,837,672	11-17-1998	Schenk et al.	
	353	5,824,322	10-20-1998	Balasubramanian	
	357	5,776,468 B1	07-07-1998	Hauser et al.	
	356	5,622,701	04-22-1997	Berg	
	320	5,593,846	01-14-1997	Schenk et al.	
	358	5,583,112 B2	12-10-1996	Kensil et al.	
	284	5,231,170	07-27-1993	Averback	

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	296	60/254,465	12-08-2000	Holtzman et al.	
	297	60/254,498	12-08-2000	Holtzman et al.	
	305	09/724,842	11-28-2000	Chalifour et al.	
	295	60/184,601	02-24-2000	Holtzman et al.	
	282	60/169,687	12-08-1999	Chain	
	242	60/168,594	11-29-1999	Chalifour et al.	
	283	09/441,140	11-16-1999	Solomon et al.	
	299	60/186,295	03-01-2000	Rasmussen et al.	

Examiner
SignatureDate
Considered

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Applicant's unique citation designation number (optional). ³ Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ⁴ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁷ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 10

Complete if Known

Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

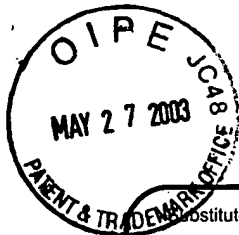
FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	352	WO	02/34777	A1	05-02-2002			
	351	WO	02/34878	A2	05-02-2002			
	343	EP	1 172 378	A1	01-16-2002			
	344	WO	01/90182	A2	11-29-2001			
	348	WO	01/77167	A2	10-18-2001			
	294	WO	01/62801	A2	08-30-2001			
	298	WO	01/42306	A2	06-14-2001			
	243	WO	01/39796	A2	06-07-2001			
	341	WO	02/03911	A2	04-07-2001			
	324	WO	00/72870	A1	12-07-2000			
	323	WO	00/72876	A2, A3	12-07-2000			
	322	WO	00/72880	A2, A3	12-07-2000			
	240	WO	00/43039	A1	07-27-2000			
	301	WO	01/62284	A2	03-01-2000			
	331	WO	99/06545	A2	11-02-1999			
	187	EP	783 104	A1	07-09-1997			
	227	WO	95/11008	A2	04-27-1995			

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 10

Complete if Known

Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	290	YOUNKIN, "Amyloid β vaccination: reduced plaques and improved cognition," <u>Nature Medicine</u> , 7:18-19 (2001).	
	292	YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid β protein, possibly showing a disappearing stage of senile plaques," <u>Acta Neuropathol.</u> , 95:217-222 (1998).	
	275	WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <u>J. Clin. Invest.</u> , 100:1804-1812 (1997).	
	223	WISCONSIN ALUMNI RESEARCH FOUNDATION, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals", U.S. Govt. Res. Develop. Rep., 70(24), 56. (Publication date unknown.)	
	274	WEINER et al., "Nasal administration of amyloid- β peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <u>Annals of Neurology</u> , 48:567-579 (2000).	
	317	VEHMAS, et al. beta-Amyloid peptide vaccination results in marked changes in serum and brain Abeta levels in APPsw/PS1 DeltaE9 mice, as detected by SELDI-TOF-based ProteinChip® technology. <u>DNA Cell Biol.</u> (11):713-21 (2001).	
	276	TJERNBERG et al., "Arrest of β -amyloid fibril formation by a pentapeptide ligand," <u>Journal of Biological Chemistry</u> , 271:8545-8548 (1996).	
	273	THORSETT, E.D. and L.H. LATIMER, "Therapeutic approaches to Alzheimer's disease," <u>Curr. Op. in Chem. Biology</u> , 4:377-382 (2000).	
	339	TENNENT et al., "Serum amyloid P component prevents proteolysis of the amyloid fibrils of Alzheimer's disease and systemic amyloidosis," <u>PNAS</u> , 92:4299-4303 (1995).	
	272	SZENDREI, et al., "The effects of aspartic acid-bond isomerization on in vitro properties of the amyloid β -peptide as modeled with N-terminal decapeptide fragments," <u>Int. J. Peptide Protein Res.</u> , 47:289-296 (1996).	
	338	STEIN and JOHNSON, "Lack of Neurodegeneration in Transgenic Mice Overexpressing Mutant Amyloid Precursor Protein is Associated with Increased Levels of Transthyretin and Activation of Cell Survival Pathways," <u>The Journal of Neuroscience</u> , 22(17):7380-7388 (September 1, 2002).	

Examiner
Signature

Date
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 4 of 10

Complete if Known

Applicati n Number	09/724,953
Filing Dat	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

271	ST. GEORGE-HYSLOP, PETER H. and DAVID A. WESTAWAY, :Antibody clears senile plaques," <u>Nature</u> , 40:116-117 (1999).	
316	SOTO, et al. Beta sheet breaker peptides inhibit fibrillogenesis in a rat brain model of amyloidosis: implications for Alzheimer's therapy. <u>Nat Med.</u> 4(7):822-6 (1998).	
319	SMALL, et al. Alzheimer's disease and Abeta toxicity: from top to bottom. <u>Nat Rev Neurosci.</u> 2(8):595-8 (2001).	
337	SKOLNICK and FETROW, "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <u>Trends in Biotech.</u> , 18(1):34-39 (2000).	
315	SINHA, et al. Recent advances in the understanding of the processing of APP to beta amyloid peptide. <u>Ann N Y Acad Sci.</u> 920:206-8 (2000).	
314	SIGURDSSON, et al. In vivo reversal of amyloid-beta lesions in rat brain. <u>J Neuropathol Exp Neurol.</u> 59(1):11-17 (2000).	
330	SIGMUND, "Viewpoint: Are Studies in Genetically Altered Mice Out of Control," <u>Arterioscler Thromb Vasc Biol.</u> , 20:1425-1429 (2000).	
313	SELKOE, The cell biology of beta-amyloid precursor protein and presenilin in Alzheimer's disease. <u>Trends Cell Biol.</u> 8(11):447-53 (1998).	
270	SCHENK, et al., " β -peptide immunization," <u>Arch. Nuerol.</u> , 57:934-936 (2000).	
312	SCHENK, et al. Immunotherapy with beta-amyloid for Alzheimer's disease: a new frontier. <u>DNA Cell Biol.</u> 20(11):679-81 (2001).	
277	SASAKI et al., "Human choroid plexus is an uniquely involved area of the brain in amyloidosis: a histochemical, immunohistochemical and ultrastructural study," <u>Brain Res.</u> , 755:193-201 (1997).	
278	SAITOH, N. and K. IMAI, "Immunological analysis of Alzheimer's disease using anti- β -protein monoclonal antibodies," <u>Sapporo Med. J.</u> , 60:309-320 (1991).	
279	SAITO et al., "Vector-mediated delivery of 125 I-labeled β -amyloid peptide Ab $^{1-40}$ through the blood-brain barrier and binding to Alzheimer disease amyloid of the A β^{1-40} vector complex," <u>PNAS USA</u> , 92:10227-10231 (1995).	
304	RASO, V.A., Grant application # 1 R43 AG1 5746-01 (non-redacted version), "Immunotherapy of Alzheimer's Disease" (publication date unknown).	

Examiner
SignatureDate
Considered

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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PA 3307758 v1



PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Compl te if Kn wn			
		Applicati n Number	09/724,953		
		Filing Dat	November 28, 2000		
		First Named Inventor	Dale B. Schenk		
		Art Unit	1647		
		Examiner Name	Christopher Nichols		
Sheet	5	of	10	Attorney Docket Number	15270J-005913US

	269	PHILIPPE, et al. "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <u>J. of Neuroscience Res.</u> , 46:709-719 (1996).	
	232	PETERSON, et al., " Recombinant Antibodies: Alternative Strategies for Developing and Manipulating Murine-Derived Monoclonal Antibodies," <u>Laboratory Animal Science</u> , 46(1):8-14 (1996).	
	336	PERUTZ et al., "Amyloid fibers are water-filled nanotubes," <u>PNAS</u> , 99(8):5591-5595 (2002).	
	280	PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <u>Biochem. Biophys. Res. Comm.</u> , 146:307-313 (1987).	
	329	NIEMANN, "Transgenic farm animals get off the ground;" <u>Transgenic Research</u> 7:73-75 (1998).	
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Sheet 6 of 10

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Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

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Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

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Filing Dat	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

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Sheet 9 of 10

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Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

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Filing Date	November 28, 2000
First Named Inventor	Dale B. Schenk
Art Unit	1647
Examiner Name	Christopher Nichols
Attorney Docket Number	15270J-005913US

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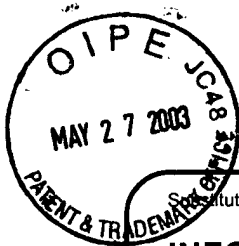
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				Filing Date	November 28, 2000
				First Named Inventor	Dale B. Schenk
				Art Unit	1647
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v	349	CHECK, "Battle of the Mind," <u>Nature</u> , 422:370-372 (March 2003).	
^	350	Nicoll et al., "Neuropathology of human Alzheimer's disease after immunization with amyloid- β peptide: a case report," <u>Nature Medicine</u> , 9(4):448-452 (April 2003).	

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First Named Inventor	Dale B. Schenk
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Attorney Docket Number	15270J-005913US

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